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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,048	08/10/2001	Thomas L. Cantor	.	7860

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EXAMINER	
COUNTS, GARY W	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/928,048	CANTOR, THOMAS L.	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 12-25* is/are pending in the application.

4a) Of the above claim(s) *1-6 and 12-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-9 and 17-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

The amendment filed January 23, 2004 is acknowledged and has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 7-9 and 17-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. On page 4, third paragraph, lines 23-28 in the specification. The applicant discloses that the present invention incorporates a discovery that a large, non-whole PTH peptide fragment, a peptide having an amino acid sequence from between (SEQ ID No. 4[PTH_{2-84}]) and SEQ ID No. 5 [PTH 34-84]), functions in vivo as an antagonist of CAP. In other words, the bind of CAP to PTH receptors and the subsequent biological activity are affected by the presence of this cyclase inhibiting PTH peptide fragment. The applicant does not disclose what this CIP fragment is. There is no description in the specification disclosing what the CIP fragment actually is.

2. Claims 7-9 and 17-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. The factors that must be considered in determining undue experimentation are set forth in *In re W*ands USPTQ2d 14000. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The instant claims are directed to a method for measuring the amount of cyclase inhibiting parathyroid hormone (CIP) fragment in a sample by adding to the sample a first antibody or antibody fragment specific for a peptide sequence for cyclase inhibiting parathyroid hormone (CIP), but does not bind to this same peptide sequence in cyclase activating parathyroid hormone, wherein the CIP comprises an amino acid sequence from between PTH_{2-84} (SEQ ID NO:4) and PTH_{34-84} (SEQ ID NO: 5); and allowing the first antibody to bind to any CIP present, thereby forming a complex that specifically binds to a portion of CIP other than the initial peptide sequence which binds to the first antibody and allowing the second antibody to bind to the complex wherein the first

antibody or the second antibody has a label or signal generating component attached thereto; and measuring the amount of labeled complex.

The disclosure fails to teach what the cyclase inhibiting parathyroid hormone fragment is. The specification on page 4, third paragraph, lines 23-28 disclose that a large, non-whole PTH peptide fragment, a peptide having an amino acid sequence from between (SEQ ID No. 4 [PTH_{2-84}]) and (SEQ ID No. 5 [PTH_{34-84}], functions in vivo as an antagonist of CAP. In other words, the binding of CAP to PTH receptors and the subsequent biological activity are affected by the presence of this cyclase inhibiting PTH peptide fragment, referred to herein as CIP. However, it is not disclosed in the specification what the fragment is.

Because the disclosure fails to teach what the fragment is, one of ordinary skill in the art would not be able to generate an antibody for the fragment without undue experimentation and thus one would have a low level of predictability in the art. Further, there are no working examples provided in the specification to provide guidance. Therefore, such is not seen as sufficient to support the breath of the claims and one skilled in the art cannot practice the claimed invention without undue experimentation, because if one does not know what the cyclase inhibiting parathyroid hormone (CIP) fragment is, then one of ordinary skill in the art could not generate an antibody for the peptide sequence in CIP without undue experimentation.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 7-9 and 19-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is vague and indefinite because it is unclear how the CIP comprises an amino acid sequence between PTH_{2-84} and PTH_{34-84}. For example, it is unclear how PTH_{2-33} would fall between PTH_{34-84}. What happens to fragments 2-33, 2-32 and so on. It is unclear what applicant is trying to encompass.

Response to Arguments

5. Applicant's arguments filed January 23, 2004 have been fully considered but they are not persuasive.

Applicant argues that as provided in the specification, a CIP fragment can comprise PTH_{2-84}, PTH_{3-84}, PTH_{4-84}, PTH_{5-84}, ...PTH_{32-84}, PTH_{33-84}, up to and including PTH_{34-84}. Further, the applicant states that this description of CIP is incorporated in the present claims (including specific SEQ ID Nos) to clarify the intended meaning of the term CIP. This is not found because Applicant has not disclosed what the CIP fragment actually is. Further, it is unclear how a sequence falls within the SEQ ID NO: 4 and SEQ ID NO: 5.

With respect to the 112 first paragraph (enablement) rejection. Applicant argues that it seems to the Applicant that the Office has taken the position that the terms "CIP" and "CIP fragment," refer to different entities, having different characteristics. Applicant states that both "CIP" and "CIP fragment refers to a peptide having an amino acid sequence from between SEQ ID NO: 4 [PTH_{2-84}] and SEQ ID NO: 5 [PTH_{34-84}] and

therefore, Applicant asserts that the claims are enabled as currently presented. This is not found persuasive because Applicants argument is not on point. Examiner has not rejected the instantly recited claims for reasons stated by Applicant, but rather has rejected the claims under 112 first enablement the disclosure fails to specifically state what the fragment is, and one of ordinary skill in the art would not be able to generate an antibody for the fragment without undue experimentation as disclosed above. Further, the instantly recited claims encompass numerous variations of the sequence, which further provides for undue experimentation to generate an antibody if one of ordinary skill does not know what the fragment is. Therefore, the 112 first paragraph enablement rejection is maintained.

Restriction status

It appears that Applicant is saying that the terms "CIP" and "CIP fragment" are the same thing and that they are not patently distinct. If applicant is traversing on the grounds that the term "CIP" and "CIP fragment" are the same and are not patently distinct, applicant should submit evidence or identify such evidence now of record showing the terms to be same or clearly admit on the record that this is the case. Therefore, if a rejection is maintained for "CIP fragment" then by default the same rejection can be used against "CIP".

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary Counts
Examiner
Art Unit 1641
February 19, 2004

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
02/20/04